Biopsy Sciences

MAR 2 9 2013

510(K) SUMMARY (21 CFR 807.92)

HYDROMARK BIOPSY SITE MARKER

510(k) Owner: Biopsy Sciences, Inc.
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Date Prepared: February, 2013

Trade Name: HydroMark Biopsy Site Marker

Common Name: Implantable clip

Classification Name: Implantable clip per 21 CFR 878.4300, NEU

Predicate Devices: Biopsy Sciences HydroMark Breast Biopsy Site Marker, K060769
Biopsy Sciences HydroMark Breast Biopsy Site Marker, K083006
Biopsy Sciences HydroMark Breast Biopsy Site Marker, K090501
Biopsy Sciences HydroMark Breast Biopsy Site Marker, K121113

Device Description: The HydroMark Breast Biopsy Site Marker contains a resorbable hydrogel component and a metallic component for permanent marking. The hydrogel has features that are unique and highly desirable for breast tissue marking.

The HydroMark Site Marker is provided pre-loaded in a sterile, disposable applicator that is compatible with specified commercially available biopsy devices. The HydroMark is deployed by the delivery system and is left in the tract created during the biopsy procedure.

This Special 510(k) addresses the addition of a smaller size HydroMark Breast Biopsy Site Marker which will be provided in a smaller, rigid, sharp delivery system for use under ultrasound

deployment either directly or though a commercially available 16 gauge x 9 cm coaxial needle.

This Special 510(k) also describes minor modifications to the delivery system used for the ATEC 9 Ga Biopsy System and the EnCore 10 Ga Directional Vacuum-Assisted Biopsy Devices, and includes compatibility testing to allow the existing Mammotome MR Targeting Set to be labeled for use with other commercial MRI biopsy devices. Associated changes to the IFU and labels are also provided.

Intended Use:

The Biopsy Sciences, Inc. HydroMark Breast Biopsy Site Marker is intended to mark tissue during a percutaneous breast biopsy procedure, be visible under ultrasound for at least 6 weeks, and be permanently visible by x-ray and MRI.

The indications are identical to those of the predicate device, the Biopsy Sciences HydroMark Biopsy Site Marker, is indicated "to mark tissue during a percutaneous breast biopsy procedure, be visible under ultrasound for at least 6 weeks, and be permanently visible by x-ray and MRI."

Technological Characteristics:

The hydrogel component expands on fluid contact to fill the track of the biopsy needle anchoring the HydroMark at the exact location of biopsy. Because the hydrogel is hydrophilic, it is clearly distinct from normal breast structure under ultrasound imaging. The hydrogel material degrades via hydrolysis over time leaving the internal stainless steel or titanium coil which provides permanent visibility under x-ray and MRI.

The smaller size marker is a new model in the family of HydroMark Breast Biopsy Site Markers which will be provided with a rigid, sharp delivery system for use under ultrasound deployment either directly or through a 16 gauge x 9 cm coaxial needle. There are no technological differences between this site marker and the others in the family of HydroMark Breast Biopsy Site Markers; therefore the addition of the smaller size marker does not raise new questions of safety or efficacy. All other modifications to the delivery systems, device compatibility and associated IFU and label changes represent minor updates to the products.

Non-Clinical Performance Data:

Non-clinical testing included the following:

- Visual and Dimensional testing

- Tensile testing of delivery system
- Penetration force
- Usability testing for ease of insertion and deployment
- Hydration testing and moisture analysis
- Visibility under ultrasound, x-ray, and MRI
- Sterilization validation

The devices performed as intended according to the specifications established for the finished device. The device continues to meet the ISO 10993-1 requirements for biocompatibility.

Conclusions:

The non-clinical bench testing, including simulated use testing, demonstrates that the 18 gauge HydroMark Breast Biopsy Site Marker for use with a 16 gauge x 9 cm coaxial needle performs as intended, accurately marking the biopsy site by fixating in the track of the needle biopsy. The device works in an identical manner to previously cleared 15 ga HydroMark Breast Biopsy Site Markers for use with 13 gauge x 9 cm coaxial needles or for direct puncture. The testing supports a determination of substantial equivalence to predicate HydroMark Breast Biopsy Site Markers cleared by FDA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Biopsy Sciences, LLC
% Ms. Sharon Rockwell
Regulatory Affairs Consultant
5582 Chalon Road
Yorba Linda, California 92886

Letter dated: March 29, 2013

Re: K130537
Trade/Device Name: Hydromark Breast Biopsy Site Marker
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable Clip
Regulatory Class: Class II
Product Code: NEU
Dated: February 18, 2013
Received: March 1, 2013

Dear Ms. Rockwell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N Melkerson -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K130537

Device Name: Biopsy Sciences HydroMark Breast Biopsy Site Marker

Indications for Use:

To mark tissue during a percutaneous breast biopsy procedure, be visible under ultrasound for at least 6 weeks, and be permanently visible by x-ray and MRI.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K130537